

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE DIET DRUGS  
(Phentermine/Fenfluramine/Dexfenfluramine)  
PRODUCTS LIABILITY LITIGATION

MDL No. 1203

THIS DOCUMENT RELATES TO:

BONNIE ELAINE THURBER LU,

Civil Action No. 2:02-CV-20147 HB

Plaintiff,

**VS.**

AMERICAN HOME PRODUCTS  
CORPORATION, et al.

**Defendants.**

**PRETRIAL ORDER NO.**

AND NOW, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that the motion of Wyeth to enforce Paragraph 7 of Pretrial Order No. 1415 against Class Member Elaine Lu is DENIED, and Elaine LU's complaint and her right to assert her claims based on PPH shall remain pending and active.

BY THE COURT:

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Harvey Bartle, III, U.S.D.J.

Dated: \_\_\_\_\_

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Plaintiff,

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**PLAINTIFF ELAINE LU'S APPEAL FROM THE REPORT AND**  
**RECOMMENDATION NO. 20 OF SPECIAL MASTER (AS TO MOTION TO**  
**ENFORCE PARAGRAPH 7 OF PRETRIAL ORDER NO. 1415 AGAINST ELAINE LU)**

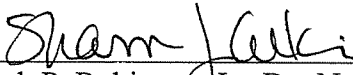
Plaintiff BONNIE ELAINE THURBER LU respectfully requests that this Honorable Court decline to adopt Report and Recommendation No. 20 of the Special Master in this action on the grounds, among others, that the Special Master has improperly weighed the evidence and judged the credibility of witnesses in deciding this matter, in violation of PTO 3699. Plaintiff respectfully requests that this Court enter an order denying Wyeth's Motion Pursuant to PTO 2383.

This appeal will be based on the attached Memorandum of Points and Authorities, the attached Exhibits referenced and incorporate therein, PTO 3699, all papers, pleadings and records on file in these proceedings and on such other and further argument and evidence as may be submitted.

Dated: November 11, 2004

Respectfully submitted,

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CORPORATION, et al.	)	
Defendants.	)	
_____	)	

**PLAINTIFF ELAINE LU'S MEMORANDUM OF POINTS AND AUTHORITIES IN  
SUPPORT OF APPEAL FROM THE REPORT AND RECOMMENDATION NO. 20 OF  
SPECIAL MASTER (AS TO MOTION TO ENFORCE PARAGRAPH 7 OF PRETRIAL  
ORDER NO. 1415 AGAINST ELAINE LU)**

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## 1.

## INTRODUCTION

The Report and Recommendation of the Special Master in this case itself amply demonstrates why it should not be adopted: In his Report and Recommendation (R&R), the Special Master weighed the evidence and judged the credibility of the witnesses in rejecting Ms. Lu's claim. The Special Master concluded that the testimony of Ms. Lu's treating cardiologist to the effect that Ms. Lu had a wedge pressure of 10 mm Hg at a specific point during her left-heart catheterization was "contrary to the objective measurements taken during Plaintiff's catheterization," was a "never documented assessment" and that his specific expert testimony regarding his specific reading of the catheterization records on the issue is "insufficient" (R&R, p. 11.)

What the Special Master's recital of the "evidence" disregards or minimizes is Dr. Badger's specific statement *in the medical records* that Ms. Lu's wedge pressure was "normal" and his specific deposition testimony. During that deposition, Dr. Badger reviewed the actual tracings from Ms. Lu's catheterization, and - as an expert cardiologist, interpreting those tracings - explained that at the point of complete expiration - the point at which wedge pressure should properly be assessed - Ms. Lu's wedge pressure was 10 mm Hg. As Dr. Badger explained, the fact that the wedge pressure may have been higher during different parts of the cycle is irrelevant. Rather, he testified, the only point at which wedge pressure is accurate is at the point of complete expiration. At that point, Ms. Lu's wedge pressure was, indeed, normal, i.e., 15 mm Hg or less - as reflected in his report.

But the Special Master has improperly substituted his judgment for that of the expert. With all due respect to the Special Master, he is not a cardiologist and is not qualified to assess, weigh or judge the credibility of Dr. Badger's report (which reflects a "normal" wedge pressure) or Dr. Badger's testimony based on the objective tracings from the catheterization. By substituting his opinion for the doctor's, the Special Master's Report and Recommendation violate's this Court holding in PTO 3699 that a genuine dispute of material facts as to whether a plaintiff suffers from PPH "is a matter for the trial court." (PTO 3699, p. 4.) Because the evidence is in dispute on the issue of Ms. Lu's wedge pressure (just as it was in dispute in the *Brown* case decided in PTO 3699), the Special Master's Report and Recommendation should not be adopted and Wyeth's motion should be denied.

Additionally, plaintiff objects to the Report and Recommendation on the following additional grounds:

1. The motion was untimely. Defendant had all the relevant information and certification of plaintiff's illness no later than November 15, 2003. PTO 2383, paragraph 5, requires that defendant use its "best efforts" to file any motion challenging a PPH claim within sixty (60) days of the receipt of a complete set of medical evidence from a Class Member. That would have required defendant to file its motion no later than January 14, 2003. Suspiciously, defendant did not file the motion in this case until March 27, 2003 - two weeks after this Court issued PTO 2793, in an obvious attempt to foreclose certain merits arguments regarding the validity and interpretation of the provisions of PTO 2383. That, however, is

not grounds for delay in the filing of the instant motion and given that there is no reasonable basis for such delay, the motion should be denied.

2. Defendant's motion was wholly unsupported by any admissible evidence. Not only did defendant fail to provide any expert opinions regarding the medical issues relevant to the determination of whether plaintiff has PPH, defendant did not even bother to authenticate, foundationalize or otherwise validate - by way of declaration or deposition - the documents attached to and submitted with the motion. Since the motion was unsupported by any admissible evidence, granting the motion would be an unconstitutional violation of plaintiff's due process rights.
3. As explained in detail below, this Court has no jurisdiction to dismiss plaintiff's claims in this action because plaintiff's interests were not adequately represented in the class settlement.

Accordingly, whether based on procedural grounds, jurisdictional grounds or evidentiary grounds, defendant's motion should be and the Special Master's Report and Recommendation should not be adopted.

2.

**PLAINTIFF HAS BEEN MEDICALLY DIAGNOSED  
WITH PPH, CONSISTENT WITH PTO 1415 AND, AT MOST  
THERE IS A DISPUTE IN THE EVIDENCE WHICH REQUIRES  
DETERMINATION BY THE TRIAL COURT PURSUANT  
TO PTO 3699**

In PTO 3699, this Court ruled that in deciding whether a plaintiff could pursue a claim for PPH damages, this Court was not in a position to determine the facts, but is authorized to operate merely as a “gatekeeper:”

We read PTO 1415 as requiring this court to decide *if there is a genuine issue of material fact as to whether plaintiff suffers from PPH . . . it is a matter for the trial court.* . . . [¶] Thus, our function is simply to serve as a gatekeeper to determine if Ms. Dugan, as a threshold matter, has come forward with sufficient evidence to proceed to trial with her PPH claim. Plaintiff’s medical evidence either before us, or before the trial court for that matter, *does not have to establish “conclusively” that her wedge pressure meets the definition of the Settlement Agreement.*” (PTO 3699, p. 4; emphasis added.)

The Special Master in this case ignored that mandate and, in the face of genuine issues of fact on the wedge pressure issue, weighed the evidence, judged the credibility of an expert and

resolved the issue. But, as discussed, below, the evidence is in dispute and, in fact, is no more ambiguous or contradictory than the evidence that this Court held in PTO 3699 to be sufficient to warrant denial of Wyeth's motion. The same reasoning should lead to the same result in this case.

**A. The evidence demonstrates that plaintiff meets the requirements of PTO 1415 for a PPH diagnosis.**

Contrary to the Special Master's conclusions, the medical evidence in this case demonstrates that plaintiff does, in fact, meet the PTO 1415 criteria for diagnosis of PPH - or, at the very least the evidence is in dispute on the issue.

**(1) Ms. Lu meets the definition of PPH in PTO 1415, paragraph I.46.a.(1)(a)**

As discussed in this Court's March 14, 2003 order (PTO 2793), a plaintiff asserting a PPH claim must, under PTO 1415, paragraph I. 46.a.(1)(a), demonstrate that the plaintiff has:

- ✓ Mean pulmonary artery pressure by cardiac catheterization of  $\geq 25$  mm Hg at rest with a normal pulmonary artery wedge pressure  $\leq 15$  mm Hg; *or*
- ✓ Mean pulmonary artery pressure by cardiac catheterization of  $\geq 30$  mm Hg with exercise with a normal pulmonary artery wedge pressure  $\leq 15$  mm Hg;

As reflected in plaintiff's medical records in this case, she has:

☐ A resting pulmonary artery pressure by cardiac catheterization of  $\geq 25$  mm Hg

✓ Each of Ms. Lu's cardiac catheterizations have revealed a resting pulmonary artery pressure in excess of 25 mm of HG.

- ▶ See, Motion, Exh. I
- ▶ See, Rubin Decl., paragraph 5.(a)
- ▶ See, Prietto Decl., Exh. 9

☐ An exercise pulmonary artery pressure by cardiac catheterization of  $\geq 30$  mm Hg

✓ Ms. Lu's cardiac catheterizations have revealed an exercise pulmonary artery pressure in excess of 30 mm of Hg.

- ▶ See, Motion, Exh. I
- ▶ See, Rubin Decl., paragraph 5.(a)
- ▶ See, Prietto Decl., Exh. 9

☐ A normal wedge pressure of  $\leq 15$  mm HG

✓ Ms. Lu's right and left heart catheterization, performed by Dr. Badger, demonstrated a normal wedge pressure of 15 mm Hg or less. As Dr. Badger confirmed, his catheterization report reflected that Ms. Lu's wedge pressure was "normal" (which is what is required under PTO 1415). Further, he specifically testified that, in fact, at the critical point of the catheterization cycle, i.e., at the point of maximum expiration, her wedge pressure was 10 mm Hg.

- ▶ See, Prietto Decl., Exh. 9 [stating in the “Conclusions” section: “Normal left ventricular filling pressures, normal pulmonary capillary wedge pressure”]
- ▶ See, Prietto Decl., Exh. 8, p. 29, lines 7-20 [finding wedge pressure to be 10 at the end of the expiration]
- ▶ See, Prietto Decl., Exh. 8, p. 45, lines 16-22 and p. 53, lines 9-18 [left ventricular end diastolic pressure measured by a left heart catheterization is the wedge pressure] and p. 31, line 17-p. 32, line 5 [measuring Ms. Lu’s left ventricular end diastolic pressure as measured by a left heart catheterization to be 10)]
- ▶ See, Prietto Decl., Exh. 8, p. 54, lines 19-23 [end exhalation wedge pressure of 10]
- ▶ See, Prietto Decl., Exh. 8, p. 55, lines 11-19 [clinically, patient had a normal wedge pressure and normal left ventricular filling pressure]
- ▶ See, Prietto Decl., Exh. 8, p. 73, line 11-p. 74, line 4 [normal pulmonary wedge, normal left-sided filling pressures, normal left ventricular end diastolic pressure]

**B. The Special Master's Report and Recommendation fails to acknowledge that there is competent medical evidence supporting the conclusion that Ms. Lu's wedge pressure was 15 or less.**

Dr. Badger is a qualified cardiologist who performed right and left heart catheterizations on Ms. Lu and who, during his deposition, interpreted his own tracings from those catheterizations. For example, Dr. Badger testified that on one part of the tracing, the wedge pressure was "15, 16." Dr. Badger then explained, however, that those figures were the result of the computer taking an average over the course of the cycle, but that "when interpreting the pulmonary artery wedge pressure, it's best to calculate it at end of exhalation." (Prietto Decl., Exh. 8, p. 27:4-p. 28:4.) Dr. Badger also explained that the estimate of 16 mm Hg in the report for the wedge pressure was only a rough estimate based on his observation in real time. (*Id.*, p. 28:5-29:6.)

Dr. Badger was then asked by defense counsel if he could tell from the tracings where the end expiration was and when he confirmed that he could, he was asked by defense counsel to mark it on the catheterization tracings. (*Id.*, 29:7-14.) When questioned by defense counsel, Dr. Badger confirmed that there were two points reflecting the end of expiration and ***that at both positions, the measurement was 10 mm Hg.*** (*Id.*, 29:15-20.)

This testimony confirms that - contrary to the Special Master's conclusion that "Plaintiff Lu has not presented any medical records demonstrating a wedge pressure measurement of 15 mm Hg or less" - the medical **records**, i.e., the catheterization tracing, when interpreted by an expert, proves that Ms. Lu's wedge pressure measurement was 10 mm Hg - well within the parameters of PTO 1415.



This situation is no different than that addressed by this Court in PTO 3699. There, this Court noted that while Wyeth's expert "has a contrary view of [the plaintiff's] wedge pressure," it was "not for this court to decide who is right and who is wrong." (PTO 3699, p. 5.) The question, this Court confirmed, is whether the plaintiff has "come forward with sufficient evidence to proceed to trial with her PPH claim," not whether she has "conclusively" established that her wedge pressure meets the definition in the Settlement Agreement. (*Id.*, p. 4.)

Dr. Badger's opinion was not simply made up or pulled out of a hat. He extensively explained - while looking at the catheterization tracings themselves (which are, of course, medical records) - the basis for his expert conclusion that Ms. Lu's wedge pressure was "normal," as reflected in his report and for his expert conclusion that the point of maximum exhalation is the proper time for measuring the wedge pressure. Finally, Dr. Badger clearly explained that, at the point of maximum exhalation, Ms. Lu's wedge pressure was undisputedly 10 mm Hg. ***And defendant has submitted no evidence to dispute that conclusion.*** Moreover, the fact that Ms. Lu's wedge pressure may have been in excess of 15 mm Hg. on other days in other tests by other doctors does not abrogate the fact that Ms. Lu met the criteria established in the settlement agreement. Rather, as this Court noted in PTO 3699, the dispute in the evidence is for the trier of fact to resolve, not a basis for this Court as "gatekeeper" to keep Ms. Lu from having a trial.

For the Special Master to weigh Dr. Badger's testimony, judge his credibility and reject that evidence is a violation of the standard this Court established in PTO 3699.

Additionally, Dr. Rubin - a highly-regarded expert - explained, in detail, why other readings of the wedge pressure in excess of 15 mm Hg can be disregarded. (Rubin Decl., pp 4-6, paragraphs 6-9.)

Thus, Ms. Lu has submitted *sufficient* evidence of PPH - even if it may not be *conclusive*. Because the evidence - at worst - demonstrates a genuine dispute, the motion should be denied, pursuant to this Court's own determination in PTO 3699.

**C. Standard differential diagnosis, as applied in the requisite medical community, for diagnosis of PPH also confirms that Ms. Lu has PPH as the result of the use of diet drugs.**

Not only does Ms. Lu meet the definition of PPH resulting from diet drug use as outlined in PTO 1415 (see, e.g., PTO 1415, p. 10, paragraph 46.b), her diagnosis is also confirmed by the definition of PPH applied in the medical community.

As elaborately detailed in the attached Declaration of Lewis Rubin, M.D. and his expert report, and based on his years of training and experience, his research regarding PPH, his examination of Ms. Lu, and his review of the enormous number of test results regarding her condition, and based on the generally accepted definition of PPH used within the community of practitioners and researchers who are experts in PPH, Ms. Lu does, indeed, have diet drug-induced PPH. (See, Rubin Decl., pp. 1-4, paragraphs 2-5.)

The Special Master failed to even consider this medical evidence demonstrating the existence of "a genuine issue of material fact as to whether plaintiff suffers from PPH." (PTO 3699, p. 4.)

**D. Further consideration should be given regarding the interpretation and application of the PTO 1415 criteria for a PPH diagnosis.**

In addition to the foregoing, and despite this Court's analysis in PTO 2793 with respect to the PTO 1415 criteria for determining whether a plaintiff has been diagnosed with PPH, there are other considerations that should be made with respect to the interpretation and application of those criteria.

First, the requirement that a "normal" wedge pressure, specified to be less than or equal to 15 mm Hg is scientifically improper. As Dr. Badger testified, a measured wedge pressure may be "normal" even if it is in excess of 15 mm Hg, depending on the placement of the cardiac catheter or the patient's own daily variabilities. (Prietto Decl., Exh. 8, p. 57, line 4 - p. 64, line 7.) Similarly, Dr. Rubin confirms that the placement of the transducer during the cardiac catheterization may have a significant impact on the wedge pressure reading. (Rubin Decl., paragraph 9.) Thus, the mandate that the wedge pressure be less than 15 mm Hg does not provide any leeway for personal variables of the patient, the technical variables of the equipment or the procedural variables of the technician and is unjustifiably rigid.

Second, the mandate that the wedge pressure be "normal" - whatever that may be on a given day - when considering the results of a cardiac catheterization fails to take into consideration the fact that an abnormal wedge pressure *does not invariably result only from left-side heart disease or conditions that can cause pulmonary hypertension*. Indeed, some patient's "baseline" wedge pressure may normally be in excess of 15 mm Hg. In the presence of a wedge pressure in excess of 15 mm Hg, further diagnostic assessment is required in order to rule out left side heart problems or conditions other than PPH. (Rubin Decl., paragraphs 6, 7.)

That such additional diagnostic analysis is appropriate is further evidenced by the fact that the criteria for establishing PPH with an echocardiogram under PTO 1415, paragraph I.46.(c) *does not require a wedge pressure reading at all*. As quoted by this Court in PTO 2793 from Dr. Barst, the “normal” wedge pressure criteria is factored in because it helps to eliminate other potential causes of pulmonary hypertension that are not related to diet drug use. Obviously, if a wedge pressure is not required in the context of an echocardiogram (because it is not available from that test), there has to be some other means of ruling out left side heart disease as the cause of pulmonary hypertension in any given case. If, in fact, such left side heart disease (or other conditions that result in an “abnormal” wedge pressure) can be ruled out through means other than a cardiac catheterization in the context of an echocardiogram, there is no basis in reason, logic or law to preclude precisely the same analysis where an abnormal wedge pressure is demonstrated on cardiac catheterization. To provide patients diagnosed through an echocardiogram the ability to rule out left side heart disease through clinical means but deny that same ability to patients undergoing cardiac catheterization is unreasonably discriminatory, and it is discrimination that has no rational basis.

Accordingly, even where a patient has an “abnormal” wedge pressure, they should be found to fall within the PPH definition in PTO 1415 so long as competent medical evidence clinically rules out any cause of the abnormal wedge pressure that could be causing pulmonary hypertension, as Dr. Rubin did here. (Rubin Decl., paragraph 7.)

3.

**WYETH'S MOTION WAS UNTIMELY AND SHOULD BE DENIED**

Even if the medical records did not substantiate the fact that Ms. Lu meets the PTO 1415 criteria for PPH claims, defendant's motion should be denied because defendant failed to comply with the requirements of this Court's PTO 2383 in bringing the motion in the first instance.

The motion procedure outlined in PTO 2383 provides, at paragraph 5, that if defendant challenges any PPH claim, it must do so by using its "best efforts" to file the motion "within sixty (60) days of receipt of a complete set of medical evidence."

As documented in the Declaration of Carlos A. Prietto, III, defendant was provided with "a complete set of medical evidence" and the PTO 2383 certification by November 15, 2002, if not sooner. (Prietto Decl., paragraphs 2-4, Exh.1, 2.) As such, any motion pursuant to PTO 2383 to challenge Ms. Lu's PPH diagnosis was required to be brought no later than January 14, 2003. Wyeth's motion was not filed until March 27, 2003 - more than 70 days after the deadline. (Prietto Decl., paragraph 5.)

Nor is there any good faith, legitimate excuse for the delay. Plaintiffs permitted defendants to take the deposition of Dr. Badger, who performed Ms. Lu's left heart catheterization, on January 29, 2003, and Dr. Rubin, her board-certified pulmonologist, on February 25, 2003. (See Motion, Exh. J; Prietto Decl., Exh. 8.) Those depositions could have been taken sooner and the only reason they were not was because of defendant's own dilatory conduct. (Prietto Decl., paragraph 5.) As such, there is no justification for the delay in bringing this motion - especially the month-long delay in filing the motion even after Dr. Rubin's deposition was taken.

The probable cause for the delay in bringing the motion - and it is not one that complies with this Court's "best efforts" requirement in PTO 2383 - was that defendant was awaiting the ruling that resulted in PTO 2793. But nothing in that pending ruling precluded defendant from bringing the instant motion in a timely way. Waiting to bring this motion until after that ruling was issued, however, has potentially prejudiced Ms. Lu because there are other grounds for challenging the application of the criteria set forth in PTO 1415 and other arguments to be made with respect to its application. (See section 2.D., above.) Having now issued its interpretation of PTO 1415, without considering these additional arguments, it is unlikely that this Court will either consider those arguments or alter its assessment of the situation. Indeed, defendant's tactical and strategic delay in bringing the instant motion has effectively put Ms. Lu in a situation where she can no longer "unring the bell" with respect to this Court's consideration of the interpretation and application of the PTO 1415 criteria for a PPH diagnosis.

There is no justification for defendant's delay in bringing this motion and the failure to comply with PTO 2383 warrants outright denial of it.

#### 4.

#### **THE MOTION SHOULD BE DENIED BECAUSE DEFENDANT HAS FAILED TO SUBMIT ANY ADMISSIBLE EVIDENCE TO SUPPORT IT**

Defendant's counsel apparently assumes that PTO 2383 somehow amended the Federal Rules of Evidence and the Federal Rules of Civil Procedure since it essentially seeks summary judgment on the issue of plaintiff's PPH diagnosis *without providing the Court with any admissible evidence*. The sole support for defendant's motion is the provision of letters between

counsel, a few pages of medical records and selected pages of a deposition - none of which is even authenticated or foundationalized. More importantly, there is not a single medical doctor's opinions supporting the claim that Ms. Lu does not meet the PTO 1415 criteria for a PPH diagnosis. In contrast, Ms. Lu submits herewith voluminous medical records and documentation, authenticated and foundationalized correspondence, medical records and deposition testimony and a qualified medical opinion about Ms. Lu's diagnosis.

It is an extreme and unwarranted violation of Ms. Lu's due process rights to have her rights determined and her claims resolved by way of a procedure that fails to comply with the mandates of F.R.C.P. 56, the summary judgment statute. Indeed, this case provides a perfect example of the problems inherent in an expedited procedure that fails to address the possibility that varying medical opinions may result from examination of precisely the same tests. In this case, Dr. Badger, based on his own examination of the tracings - in real time - that occurred during Ms. Lu's right and left heart catheterization, concluded that her wedge pressure was 10 mm Hg and normal. Notably, that was the only *left heart* catheterization performed and is the best way to determine the presence of left-sided heart disease. Although defendant contests the validity and reliability of Dr. Badger's conclusions, ***there is nothing in PTO 1415 or PTO 2383 that permits this Court to resolve disputed issues of fact in abrogation of plaintiff's due process rights or rights under F.R.C.P. 56.***

There are only two possible ways to resolve this issue and still preserve plaintiff's due process rights. This Court must provide, with respect to the motion process it established under PTO 2383, that either:

(1) A prima facie showing that a plaintiff meets the PTO 1415 criteria by a qualified medical doctor, even if contested by defendant, is sufficient; or,

(2) The motion must meet the evidentiary and other rigorous requirements of F.R.C.P. 56.

Here, plaintiff would prevail under either standard. As evidenced by Dr. Badger's sworn testimony, Ms. Lu's wedge pressure reading was 10. That being the case, she established a prima facie compliance with the PTO 1415 criteria. That evidence also, however, demonstrates the existence of a genuine issue of fact on that subject, thus requiring resolution by a jury.

Thus, either way, Wyeth's motion should be denied.

5.

**THIS COURT HAS NO JURISDICTION TO IMPOSE THE PPH CRITERIA  
ON PLAINTIFF BECAUSE SHE WAS NOT ADEQUATELY REPRESENTED**

In addition to the foregoing issues, plaintiff, for purposes of preserving her rights on appeal, contends that this Court does not have the jurisdictional power to impose the class settlement on plaintiff.

**A. The All Writs Act does not obviate either Fed.R.Civ.P. 65 or the rules that generally apply in entering what amounts to an injunction against plaintiff. Under these rules, the Declaration of Lewis Rubin, M.D. is dispositive.**

If this Court does not apply F.R.C.P. 56 standards to the determination of the issues presented in this motion, its ruling will amount to the issuance of an injunction against plaintiff to preclude her from proceeding with her claims. But this Court does not have the jurisdictional power to do that.



The All Writs Act does not obviate Fed.R.Civ.P. 65. (*Florida Medical Association, Inc. v. U.S. Department of Health, Education and Welfare*, 601 F.2d 199 (5<sup>th</sup> Cir. 1979).) The ordinary rules necessary to justify an injunction must still apply. Any injunction must be based on competent proof, beyond simply the attachment of limited medical records and the Fed.R.Civ.P. 11 attestation of counsel. This Court should still apply the Federal Rules of Evidence and review Wyeth's motion, in case of disputed fact, in a light most favorable to the Plaintiff.

The All Writs Act does not change the basic rules of procedure or evidence. As stated in *Florida Medical Association, Inc., supra*:

[T]he All Writs Act does not free a district court from the restraints of Rule 65.

The statute authorizes federal district courts to "issue all writs necessary or appropriate in aid of their respective jurisdictions and agreeable to the usages and principles of law." 28 U.S.C. 1651(a) (1976). While the All Writs Act empowers a district court to fashion extraordinary remedies when the need arises, *it does not authorize a district court to promulgate an Ad hoc procedural code whenever compliance with the Rules proves inconvenient.* (*Id.* at 202; emphasis added.)

Dr. Rubin's Declaration in and of itself disposes of this PTO 2383 motion. If this Court were to grant the motion on the present record, it could only do so by rejecting Dr. Rubin's Declaration and finding it inadmissible to sustain Plaintiff's case. Courts have universally held it error to reject qualified expert proof. (*See, e.g., Holbrook v. Lykes Bros. S.S.Co.*, 80 F.2d 777 (3<sup>rd</sup> Cir.)) This is especially so on issues of causation in drug product cases. (*See, e.g., Kennedy v. Collagen Corp.*, 161 F.3d 1226 (9<sup>th</sup> Cir. 1998), *cert. denied*, 119 S.Ct. 1577 (1999); *Ambrosini v.*

*Labarraque*, 101 F.3d 129 (D.C. Cir. 1996); *Glaser v. Thompson Med. Co.*, 32 F.3d 969 (6<sup>th</sup> Cir. 1994).)

Defendant does nothing more than tender a few pages of Ms. Lu's medical records and a portion of one deposition and posits that this is sufficient for this Court to arrive at a medical diagnosis; namely, that Ms. Lu suffers from pulmonary hypertension secondary to some other, unspecified, cause. Obviously, in order to make such a finding, this Court would have to conclude that, for some reason, the disputed facts presented by Dr. Rubin's affidavit is insufficient to present the case to a jury. This conclusion possibly may be made at some point without a trial on the basis of a summary judgment motion or a *Daubert* hearing. But here, Defendant seeks the same result on the basis of even less of a record than either a summary judgment or a *Daubert* hearing would normally require.

Such a result is especially dangerous. Courts are generally reluctant to substitute the medical diagnosis of a judge in the context of summary judgment, and in lieu of a competent medical expert. For instance, the court in *Cortes-Irizarry v. Corporacion Insular*, 111 F.3d 184 (1<sup>st</sup> Cir. 1997), cautioned against determining a medical diagnosis in the setting of summary judgment:

Given the complex factual inquiry required by *Daubert*, courts will be hard-pressed in all but the most clearcut cases to gauge the reliability of expert proof on a truncated record. Because the summary judgment process does not conform well to the discipline that *Daubert* imposes, the *Daubert* regime should be employed only with great care and circumspection at the summary judgment stage.

Since two qualified doctors have concluded that Ms. Lu does, in fact, have PPH (Dr. Badger on the basis that his left heart catheterization meets the PTO 1415 criteria and Dr. Rubin on the basis of all the other test results and his examination of Ms. Lu), there is no basis for this Court to substitute its judgment for that of these two qualified medical opinions.

**B. The “check box” approach of PTO 2383, if applied as an absolute determiner, is violative of due process rights.**

Clarification is needed with respect to this Court’s establishment of the “check box” in Appendix B of PTO 2383. If that “check box” is merely intended to be nothing more than a guide or preliminary assessment of the issues in order to *rule in* claims as being PPH and thus excluded from the Class Settlement, there is certainly nothing inappropriate about that. But if the “check box” chart is applied such that it is a mandate and necessarily *rules out* PPH claims, it improperly usurps the medical judgment of doctors and unjustifiably impairs the due process rights of Plaintiffs.

Indeed, as explained by Dr. Rubin:

The “check box” proposed by Wyeth is somewhat simplistic and cannot take into account the range of clinically occurring variations. A simple “yes” or “no” analysis is dangerous without being flexibly applied in the full background of the medical facts. Specifically, the measurement of the pulmonary wedge is a relevant factor in diagnosing PPH. The wedge measurement is significant in providing data related to whether some condition or problem on the left side of the heart (such as left ventricular diastolic dysfunction) is causing the pulmonary hypertension. However, a wedge measurement is not the only relevant data that is

used to rule out left ventricular diastolic dysfunction and other conditions in the left side of the heart as causes of pulmonary hypertension. Because the simplistic “check box” approach does not appropriately allow for and factor into account all potential, relevant data used to rule out a left sided heart condition as the cause of pulmonary hypertension, this approach can not be used in isolation to determine on clinical grounds whether a person has PPH.

(See, also, Declaration of Shelly Shapiro, M.D., filed in opposition to defendant’s motion pursuant to PTO 2383 in *Sheila Brown v. American Home Products*, Civil Action No. 99-20593, which is incorporated herein by reference.)

Thus, the meaning, effect and use of the “check box” must be clarified.

**C. Plaintiff has never been adequately represented by counsel in MDL 1203 with respect to the settlement. This presents a real question of due process for non-resident plaintiffs in a class action.**

Defendant and Class Counsel relied heavily on *In re: Prudential Insurance Company of America Sales Practice Litigation*, 261 F.3d 355 (3<sup>rd</sup> Cir. 2001) in concluding that PPH claimants could be subjected to limitation or elimination of their claims based on the criteria set forth in PTO 1415. Yet, that case involved Plaintiffs who were class members and who had already made an appearance in the class action, actually “opting in” for part of the class benefits.

Here, Plaintiff never made an appearance prior to the settlement approval and is asserting her claim only after a diagnosis of PPH which occurred AFTER the Fairness Hearing in the captioned litigation. Thus, *In re Real Estate Title and Settlements Services Antitrust Litigation* (“Real Estate Title”), 869 F.2d 760 (3<sup>rd</sup> Cir. 1989) more directly addresses the issues here.

The defendants in *Real Estate Title*, like Wyeth here, attempted to enjoin non-resident Plaintiffs from proceeding with their remedies in the Plaintiffs' home forum of their choice. The *Real Estate Title* defendants argued that an injunction was necessary per the All Writs Act to preserve the jurisdiction of the Court and maintain the integrity of a settlement entered in the Multi-District Litigation. The Third Circuit Court of Appeals reversed the District Court's entry of an injunction, on due process grounds. Judge Becker eloquently discussed the requisite due process requirements in the context of a Class Action, applying the Supreme Court decision of *Phillips Petroleum Company v. Shutts*, 472 U.S. 797 (1985). As stated by Judge Becker:

*Shutts* stands for the proposition that a court can bind all members of a plaintiff "opt out" class to a judgment for damages even if the class members do not meet the traditional requirements of *in personam* jurisdiction "so long as the named parties adequately represented the absent class and the prosecution of the litigation was within the common interest." (*Real Estate Title*, at 766 (quoting *Shutts* at 808; emphasis added.)

Thus, the two vital due process requirements are: (1) an opportunity to "opt out"; and (2) adequate representation.

Judge Becker further stated that adequate representation was vital to the due process analysis and that a challenge to this representation can and should be allowed in a collateral attack in a forum of the Plaintiffs' own choice:

However, as the Court in *Shutts* pointed out, the absent class members in *Shutts* were bound by the class action judgment only if they were adequately represented in the class action proceeding. Indeed, the Supreme Court had previously held

that it would violate due process to bind an absent class member to a judgment from a proceeding in which the member was not adequately represented. *See Hansberry v. Lee*, 31 U.S. 32, 42-44, 61 S.Ct. 115, 118-19, 85 L.Ed. 22 (1940). Thus the class members in *Shutts* still possessed their right to attack the class action judgment collaterally, presumably in the forum of their choice, alleging that the representative plaintiff did not represent them adequately. (*Id.* at 767; emphasis added.)

If Wyeth's request for what amounts to an injunction is granted, the question will emerge whether plaintiff was adequately represented in the Fairness Hearing. This question must be answered before any injunctive-type proceeding can be applied, per constitutional due process. More accurately put, the question must be addressed of whether these PPH Claims/Clients were represented *AT ALL* in this MDL 1203. Finally, intertwined with these issues per Judge Becker's opinion is whether this Court can foreclose any non-resident Class Members, such as Ms. Lu, from collaterally attacking the adequacy of (or the lack of) representation in a Class Action.

Wyeth's and Class Counsel's immediate answer to this question would be, of course, that Ms. Lu had a right to "opt out" of the class and failed to do so. The failure to opt out arguably conferred constitutional jurisdiction allowing the sought-after injunction. Although these types of "claims" on the face of the Complaint were never sought to be a part of the class, proponents of an injunction may claim that the PPH Plaintiffs were still a part of the class and represented by Class Counsel. Accordingly, although Ms. Lu's *claim* was not represented, the *claimant* was still a part of the class and still adequately represented. *In other words, the clients were represented, but their claims were not.*

Of course, Class Counsel are some of the best lawyers in the country. There is no debate about that. But with all due respect, due process in this case, and the imposition of an injunction, is a real live problem simply because the best lawyers in the country did not *ever* represent PPH Claims or Claimants in the Fairness Hearing - ***because the PPH claims were never the subject of the class pleadings.***

The Class Members were those claiming VHD, not PPH. As stated in Judge Bechtle's excellent opinion, *In Re: Diet Drugs, MDL 1203*, 2000WL 1222042, \*46 (E.D.Pa., August 28, 2000) (PTO 1415) in discussing why the VHD claims were appropriate for class treatment:

The instant class does not suffer from the same problems that exposure-only class members suffered from in *Amchem*. In [*Amchem Prods., Inc. v. Windsor*, 521 U.S. 591 (1997)], the Court found that class members *could not fairly be bound by a settlement where some members were unaware of their exposure to asbestos or where their potential injuries could have a latency period of 30 to 40 years.*

Here, all class members are aware of their exposure to Pondimin or Redux, which have been off the market since September 1997. In addition, the class members have a diagnosable condition that can be detected through an echocardiogram.

Obviously, the class members discussed by Judge Bechtle, as quoted above, could not have been PPH Claimants. Those Claimants very clearly have a "latency period" problem. Symptoms of PPH may not be identified as such for many years after exposure to Fen-Phen, and it may take a few more years from first presentation to a medical provider to diagnosis of PPH. Latency was discussed, but not extensively in the context of PPH by Judge Bechtle: "[T]he

scientific evidence does not indicate a long latency period or slow progression of VHD.” PTO 1415, 2000WL 1222042 \*56.

Elsewhere in the Opinion, Judge Bechtle discusses the importance of latency to the due process analysis:

In *Amchem Products, Inc. v. Windsor*, the Supreme Court recognized that adequate notice to the class could be impeded where many class members were not even aware of their exposure to a defendant’s product. *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 628 (1997). The initial opt out right in *Amchem* was not meaningful due to the fact that some asymptomatic class members were unaware that they were even exposed to asbestos. *Id.* Here, however, there are no class members unwittingly exposed to the diet drugs, which were available only through a doctor’s prescription and had to be consciously ingested. In addition, class members were made aware of the risks these drugs posed in 1997, when AHP withdrew them from the market. Moreover, Class Counsel employed an expansive notice plan to inform class members of their initial opt out right. In sum, unlike *Amchem*, the initial opt out right has meaning because all class members were aware of their exposure to the diet drugs. *In Amchem, the Supreme Court also raised the concern that even if class members “fully appreciate the significance of class notice, those without current afflictions may not have the information or foresight needed to decide, intelligently, whether to stay in or opt out.”* (PTO 1415, 2000WL 1222042 \*39; emphasis added.)



Again, Judge Bechtle could not have been discussing Ms. Lu, who fit exactly within the situation discussed in *Amchem*. Clearly, since plaintiff was diagnosed only after the Fairness Hearing, she fit in the *Amchem* category of those who could not have made a considered decision during the opt out period.

Perhaps Wyeth's lawyers and Class Counsel would say that such claimants are not prevented from fully prosecuting their claims. All the injunction seeks, according to its proponents, is to sort Settled Claims from Non-Settled Claims according to the PPH definition imposed through the Fairness Hearing. The problem here is that, if this Court were to impose an injunction, or the equivalent of a summary judgment, that order would impose the Settlement from the Fairness Hearing on PPH Claimants/Claims who were not adequately represented at the Fairness Hearing. As set out in *Real Estate Title*, before *any* Court can hope to exercise jurisdiction over non-resident Plaintiffs, there must be a showing of due process in personam jurisdiction. And this can only constitutionally happen where: (1) there was a meaningful opportunity to opt out according to *Amchem, supra*, and (2) there was some adequate representation in the Fairness Hearing that established the PPH definitions that Wyeth now seeks to impose. The Settlement itself sorts Settled from Non-Settled Claims by its definition. But that definition cannot have a binding effect *unless it is imposed on parties via the prerequisites of due process*. As shown above, such opt out and such representation were not provided through the Fairness Hearing in MDL 1203. Therefore, the threshold question of whether this Court has jurisdiction to impose injunctive relief on non-resident Plaintiffs has not been met.

A more complete (and objective) discussion of these due process problems, directly applicable here, is found in Henry Paul Monaghan, *Antisuit Injunctions and Preclusion Against Absent Nonresident Class Members*, 98 Colum. L. Rev. 1148 (1998). There, Professor

Monaghan persuasively argues that non-resident class members (such as Ms. Lu) cannot be precluded from collaterally attacking in a forum of their own choosing, a Class Action certification or settlement on the basis of due process.

**D. An injunction is not “necessary” to protect this Court’s jurisdiction because PPH claims, brought in state court forum, will not render this Court’s jurisdiction nugatory.**

In *Carlough v. Amchem Products, Inc.*, 10 F.3d 189, 202 (3<sup>rd</sup> Cir. 1993), the Court explained that injunctive relief, under the All Writs Act, can only be justified under very special circumstances:

In *In re Glenn Turner*, 521 F.2d 775 (3<sup>rd</sup> Cir. 1975), we examined the “necessary in aid of the court’s jurisdiction” exception to the Anti-Injunction Act. There the Attorney General instituted a collection suit in a state court following a money judgment and just days after the federal district court had certified the federal class action. Nevertheless, execution upon the state court judgment was effectively enjoined by order of the district court, purportedly by authority of the Anti-Injunction Act. In reversing the injunction of the district court, we reiterated that for the “necessary in aid of jurisdiction” exception to apply, “it is not enough that the requested injunction is related to that jurisdiction, but it must be “*necessary in aid of*” that jurisdiction.” *In re Glenn Turner*, 521 F.2d at 789 (citing *Atlantic Coast Line R.R. Co.*, 398 U.S. 281, 295, 90 S.Ct. 1739, 1747, 26 L.Ed2d 234 (1970)). We noted that the exception authorizing injunctions necessary in aid of the court’s jurisdiction applies only “to prevent a state court

from so interfering with a federal court's consideration or disposition of a case as to seriously impair the federal court's flexibility and authority to decide that case.'" *Id.* Finally, we held that Fed.R.Civ.P. 23(b)(3) does not prohibit state proceedings when an action for the same cause is pending in federal court. In recognition of the independence and equivalent stature of the state and federal courts, we held that actions derived from the same cause against the same defendants may be maintained simultaneously in federal and state court. The effect of a judgment in one would be determined by the principle of *res judicata*.

In *Carlough*, class members absent from an action pending in the Eastern District of Pennsylvania filed a competing class action in West Virginia to declare that all residents of West Virginia had "opted out" of the *Carlough* class. In *Carlough*, claims identical to those asserted in the Eastern District were also being asserted in West Virginia. In upholding the injunction, the *Carlough* Court cautioned: [S]imultaneous federal and state adjudications of the same in personam cause of action do not of themselves trigger the necessary in aid exception, and the letter and spirit of the Anti-Injunction Act and All-Writs Act counsel a restrictive application of that exception." *Id.* Here, unlike *Carlough*, the pending state Court actions are not "direct attacks" on this Court's jurisdiction. Where due process prerequisites have first been reviewed and satisfied, a state court with concurrent jurisdiction could just as easily apply the definitions of PPH. There is no reason to think that such Court would not or could not apply these definitions, just as easily as the Special Master. Injunctive relief should be considered only in truly exceptional circumstances, where the state court action can be seen as a direct attack on this Court jurisdiction. Otherwise, why should this Court assume that other courts would not apply

the rules of res judicata and give full faith and credit to the judgments in MDL 1203. Indeed, state enforcement of federal rights, whether by federal statute, or through a settlement in a federal class action, is not an “extraordinary circumstance” justifying relief under the All Writs Act.

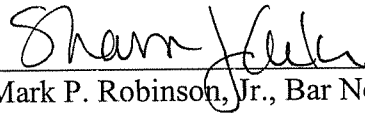
6.

### CONCLUSION

The procedural, jurisdictional and substantive flaws in the instant motion warrant its complete denial and plaintiff respectfully request that it be denied.

Dated: November 11, 2004

Respectfully submitted,



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IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE DIET DRUGS

(Phentermine/Fenfluramine/Dexfenfluramine)

PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:

BONNIE ELAINE THURBER LU,

Plaintiff,

vs.

AMERICAN HOME PRODUCTS

CORPORATION, et al.

Defendants.

MDL No. 1203

Civil Action No. 2:02-CV-20147 HB

**DECLARATION OF ANITA SHERBANEE**

**RE EXHIBITS SUBMITTED IN SUPPORT OF PLAINTIFF ELAINE LU'S APPEAL**  
**FROM THE REPORT AND RECOMMENDATION NO. 20 OF SPECIAL MASTER (AS**  
**TO MOTION TO ENFORCE PARAGRAPH 7 OF PRETRIAL ORDER NO. 1415**  
**AGAINST ELAINE LU)**

I, Anita Sherbanee, declare and state as follows:


1. I am an attorney at law licensed to practice in the State of California. If called upon as a witness, I would testify to the following.
2. Concurrently with the filing of Plaintiff Elaine Lu's Appeal from the Report and Recommendation No. 20 of Special Master (As to Motion to Enforce Paragraph 7 of Pretrial

Order No. 1415 Against Elaine Lu), Plaintiff is filing the true and exact copies of the following documents in support of her appeal:

1. Plaintiff Elaine Lu's Opposition to Wyeth's Motion Pursuant to PTO 2383 and the exhibits attached thereto; Declaration of Lewis J. Rubin in Support of Plaintiff Elaine Lu's Opposition to Wyeth's Motion Pursuant to PTO 2383 and the exhibits attached thereto.
2. Declaration of Carlos A. Prietto, III in Support of Plaintiff Elaine Lu's Opposition to Wyeth's Motion Pursuant to PTO 2382 and the exhibits attached thereto.
3. Plaintiff's Letter Surreply to Wyeth's 2383 Motion, dated May 1, 2004.

I declare and certify under penalty of perjury that the foregoing is true and correct.

Dated: November 11, 2004

  
\_\_\_\_\_  
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CERTIFICATE OF SERVICE

I, Carlos A. Prietto, III, hereby certify that a true and correct copy Plaintiff Elaine Lu's Appeal from the Report and Recommendation No. 20 of Special Master (As to Motion to Enforce Paragraph 7 of Pretrial Order No. 1415 Against Elaine Lu) was served by the described method, upon the persons listed below, on this 11<sup>th</sup> day of November, 2004:

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